



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Xigris
Docket No. 02E-0284

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

FEB -1-2003

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,681,932, filed by Eli Lilly & Company under 35 U.S.C. § 156. The human biological product claimed by the patent is Xigris (droctrecogin alpha), which was assigned biological license application (BLA) No. 125029/0.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The BLA was approved on November 21, 2001, which makes the submission of the patent term extension application on January 11, 2002, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Brian P. Barrett
Eli Lilly & Company
Patent Division, BPB
Lilly Corporate Center
Indianapolis, IN 46285

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Arlington, VA 22202, on the date appearing below.

ELI-LILLY AND COMPANY

By

YSB Roades

Date

4-11-03

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U. S. Patent No. : RE37,806E
Issued: : July 23, 2002
On an Application of : Brian W. Grinnell
Serial No. : 09/384,327
Filed : August 26, 1999
Entitled : METHOD OF USING EUKARYOTIC
EXPRESSION VECTORS COMPRISING
THE BK VIRUS ENHANCER
Docket No. : X-06606M

REQUEST FOR CERTIFICATE OF CORRECTION

UNDER 37 C.F.R. 1.322

Assistant Commissioner for Patents

Arlington, VA 22202

Sir:

The patentee of the above-identified patent respectfully requests that you issue a Certificate of Correction to correct errors that occurred during the printing of the patent. Attached are two copies of Form PTO 1050 on which the errors are specified.

RECEIVED

APR 15 2003

Office of Patent Publication
Director's Office

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

Respectfully submitted,

Paula K. Davis

Paula K. Davis
Agent for Patentee
Registration No. 47,517
Phone: 317-433-3422

March 12, 2003

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US RE37,806E
DATED : July 23, 2002
INVENTOR(S) : Brian W. Grinnell

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 1, the word "The" which is printed in brackets should have been deleted as indicated by placing the brackets around it as required under 37 CFR 1.173(d)(1) in the initial filing of the claims in the Reissue Application on August 26, 1999 (Exhibit A).

Claims 5-33 are printed in italics but should be printed in normal font.

In the abstract, 1st sentence, the word "enhances" should be "enhancer".

In the abstract, 2nd sentence, the word "produce", should be "product".

In the Other Publications, Kawaski, et al 1976, "J. Biol. Chem" should be "J. Biol. Chem".

In the Other Publications, Vajaj et al., "J. Biological Chem" should be "J. Biol. Chem".

In column 2, line 49, "DeLuca, at al.," should be "DeLuca, et al.,".

In column 10, line 46, "polymerass" should be "polymerase".

In column 17, Table 2, "13.8:" should be "13.8".

In column 18, line 49, "riboquanyl" should be "riboguanyl".

In column 23, line 28, "IPT/ml", should be "IPTG/ml."

In column 24, line 34, "The μ l mg" should be "The ~1 mg".

In column 26, line 21, "buffer (50 mM NH₄OAc;" should be "buffer (500 mM NH₄OAc;".

In column 26, line 50, "About i mg of plasmid" should be "About 1 mg of plasmid".

In column 31, line 45, "Fifth" should be "Fifty".

In column 32, Example 7, line 43, "80 of H₂O." should be "80 μ l of H₂O."

In column 41, line 35, "to,express" should be "to express".

In column 41, line 56, "RR1AM15/pUC19TPAFE" should be "RR1 Δ M15/pUC19TPAFE".

MAILING ADDRESS OF SENDER:

Eli Lilly and Company
Patent Division

P.O. Box 6288

Indianapolis, Indiana 46206-6288

PATENT NO. RE37,806E

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US RE37,806E
DATED : July 23, 2002
INVENTOR(S) : Brian W. Grinnell

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- In column 42, line 11, "pUCATPAFE" should be "pUC19TPAFE".
- In column 42, line 19, "and 60 mM MgCl₂," should be "and 60mM MgCl₂,"
- In column 43, line 10, "EcoqRI" should be "EcoRI".
- In column 46, line 50 "digestion as 30 described" should be "digestion as described".
- In column 47, line 52, "pKC293PX" should be "pKC283PX".
- In column 48, line 7, "accordance with the ligatiopro-" should be "accordance with the litigation".
- In column 48, line 17, "in 20 µl 1 10x high-salt" should be "in 20 µl 10x high-salt".
- In column 48, line 50, "excision of ~21 kb" should be "excision of ~2.1 kb".
- In column 49, line 45, "XbaI-BaHI" should be "XbaI-BamHI".
- In column 49, line 55, "Plasmid pPR13" should be "Plasmid pPR12".
- In column 49, line 56, "plasmid pBr322" should be plasmid pBR322".
- In column 51, line 7, "BdglII digestion" should be "BglII digestion".
- In column 51, line 35, "dihydrofalate" should be "dihydrofolate".
- In column 51, line 48, "5 µl H₂O was added;" should be "5 µl H₂O was added:".
- In column 51, line 54, "(~25 µg)" should be "(~0.25 µg)".
- In column 52, line 20, "(NRRL B-15201)" should be "(NRRL B-15210)".
- In column 52, line 30, "20 units BqlII" should be "20 units BglII".
- In column 52, line 54, "wer digested" should be "were digested".
- In column 53, Example 11, line 18, "60 of H₂O" should be "60 µl of H₂O".

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INVENTOR(S) : Brian W. Grinnell

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- In column 53, Example 11, line 37, "(~50 units) in" should be "(~50 units) of".
- In column 54, Example 11, line 41, "About 50 µl" should be "About 5 µl".
- In column 56, Example 13, line 28, "Bali" should be "BaII".
- In column 57, line 15 "DAN should be "DNA".
- In column 57, line 35 "About 0.01" should be "About 0.1".
- In column 58, line 48, "dud" should be "that".
- In column 59, line 3, "K12 HB101pBLTdhfr1" should be "K12 HB101/pBLTdhfr1".
- In column 59, line 27, "10x Hgal buffer" should be "10x HgaI".
- In column 60, line 47, "from the get" should be "from the gel,".
- In column 60, line 50, "20 µof H₂O; should be "20 µl of H₂O;".
- In column 60, line 50, "monograms" should be "nanograms".
- In column 61, line 4, "2 µof" should be "2 µl of"
- In column 61, line 6, "H₂O 20, and 1 µ(~1 Weiss" should be "H₂O, and 1 µl (~1 Weiss".
- In column 61, line 16, "MM941/pTPA603" should be "MM294/pTPA603".
- In column 61, line 28, "IN" should be "10X".
- In column 61, line 33, "10 PI of H₂O" should be 10 µl of H₂O,".
- In column 61, line 39, "5 µl g" should be "5 µg".
- In column 61, line 41, "100 µof H₂O" should be "100 µg of H₂O"..

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PATENT NO. : US RE37,806E
DATED : July 23, 2002
INVENTOR(S) : Brian W. Grinnell

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 61, line 42, "About 5 μ l g" should be "About 5 μ g".
In column 62, line 8, "10 μ l g" should be "10 μ g".
In column 62, line 10, "(~50 units of" should be "(~50 units) of".
In column 62, line 35, "des sired" should be "desired".
In column 62, line 52, "10 μ of" should be "10 μ l of".
In column 62, line 64, "1 μ of" should be "1 μ l of".
In column 62, line 65, "~135 kb" should be "~1.35 kb".
In column 63, line 3, "sift" should be "site".
In column 63, line 11, "~135 kb" should be "~1.35 kb".
In column 64, line 54/55, "82 μ l g" should be "82 μ g".
In column 64, line 56, "20 μ of" should be "20 μ l of".
In column 64, line 58, "Na₂EDTA" should be "Na₂EDTA)".
In column 65, line 1, "10 μ of" should be "10 μ l of".
In column 65, line 2, "1 μ of" should be "1 μ l of".
In column 65, line 45, "present invention," should be "present invention."
In column 66, line 15, "40 μ l g ml" should be "40 μ g ml".
In column 66, line 28, "4 how" should be "4 hours".
In column 66, line 46, "400 μ /ml." should be "400 μ g/ml."

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DATED : July 23, 2002
INVENTOR(S) : Brian W. Grinnell

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- In column 66, line 47, "medium, changes" should be "medium changes".
- In column 66, line 66, "in like" should be "in the".
- In column 67, line 1, "studied efficient" should be "studied, efficient".
- In column 67, line 3, "selectable maker" should be "selectable marker".
- In column 67, table 5, line 52, "Chloramphenicaol" should be "Chloramphenicol".
- In column 68, table 5, line 21 "Only th 293" should be "Only the 293".
- In column 68, table 5, line 26 ""SV1, and" should be "SV1, an".
- In column 68, table 5, line 27/28 "Poly-marviruses" should be "Polyomaviruses".
- In column 71, line 8, "~72 kb" should be "~7.2 kb".
- In column 71, line 12, "Saul" should be "SauI".
- In column 72, line 14, "paragraph Plasmid" should be "paragraph. Plasmid".

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